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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,219	01/12/2004	Donald R. Sandell	4696C1	1150

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FOSTER CITY, CA 94404

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,219

Applicant(s)

SANDELL, DONALD R.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 36-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurz et al. (US 6,767,512 or WO 98/20975) in view of Woudenberg et al.(US 5,928,907) and Yamamoto et al.(US 5,102,623) or Pfoest et al.(US 5,496,517).

The reference of Lurz et al. discloses a thermal cycling device (4) that includes a sample block assembly (7,8,9,21,22,23,26) and a sample well tray holder (5) configured to hold a sample well tray. The sample block assembly is independently translatable.

While the reference of Lurz et al. discloses a fixed cover or platen (12) that is heated, the reference is silent as to the presence of an optical detection system that is required of independent claims 36, 43, 45 and 52.

The reference of Woudenberg et al. discloses that it is known in the art to configure a cover or platen (14) that is heated within an integrated optical detection system (10, 8, 6, 4, 2) (See Figure 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the cover or platen (12) of the reference of Lurz et al. with an optical detection system as suggested by the reference of Woudenberg et al. for the known and expected result of providing a means recognized in the art for providing real-time fluorescence detection of the thermal cycling reaction within the sample wells.

Claims 36, 43, 45 and 52 further differ by reciting that the sample well tray holder (5) is independently translatable relative to the sample block assembly and positions a sample well tray into alignment with the sample block assembly and the optical detection system.

The reference of Yamamoto et al. discloses that it is known in the art to automate the introduction of liquid reagents into a sample well tray (14) using a sample well tray holder (11) that is independently translatable with respect to a sample block (26) at a sample heating station.

The reference of Pfost et al. discloses a device capable of thermal cycling that includes a sample block assembly(60); and a sample well tray holder (34) for holding a sample well tray (44). The sample block assembly and sample well tray holder are independently translatable to position a sample well tray in a position for temperature control of the sample well tray (See Figure 6).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the modified primary reference so as to automate the introduction of the reagents into the sample well tray as

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suggested by the reference of Yamamoto et al. or Pfost et al. for the known and expected result of providing automation of the sample preparation steps prior to the thermal cycling process and/or while providing a stable environment for storing unstable enzyme reagents (See column 1, lines 45-55, of Yamamoto et al.).

Modification of the reference of Lurz et al. to include an optical detection system and translatable sample tray holder as suggested by the references of Woudenberg et al., Yamamoto et al. and Pfost et al. would result in a device and method of use wherein the sample block assembly and sample well tray holder are independently translatable to position a sample well tray with nucleic acid amplification samples into alignment with the sample block assembly and the optical detection system.

With respect to claims 37, 44, 46 and 53, the optical detection system would remain stationary during the movement of a sample well tray within the device.

With respect to claims 38 and 47, the sample block assembly includes sample block (7, 8 or 9) for contacting the sample well tray.

With respect to claims 39 and 48, the device includes a positioning mechanism (22, 23, 26) configured to translate the sample block (7, 8, 9).

With respect to claims 40 and 49, the positioning mechanism includes a plurality of links (22).

With respect to claims 41 and 50, the positioning mechanism includes a motor (27) for moving the links.

With respect to claims 45 and 52, translation of the sample well tray holder as suggested above would bring the optical detection system and nucleic amplification sample into direct optical alignment.

With respect to claim 51, the resulting device would be a real-time PCR machine.

Response to Arguments

4. With respect to the rejection of Claims 36-53 under 35 U.S.C. 103(a) as being unpatentable over Lurz et al. (US 6,767,512 or WO 98/20975) in view of Woudenberg et al.(US 5,928,907) and Yamamoto et al.(US 5,102,623) or Pfoest et al.(US 5,496,517), Applicant argues that the rejection is improper for several reasons.

Applicant first argues (See page 7 of the response filed 5/25/06) that neither the references of Lurz et al., Pfoest et al., Yamamoto et al. nor Woudenberg et al. “teach and independently translatable sample block assembly and independently translatable sample well tray holder that position a sample well tray with nucleic acid amplification samples into alignment with the sample block assembly and the optical detection system”. Applicant stresses that Lurz et al. at best discloses a translatable thermostated block and a stationary holding plate; Pfoest et al. and Yamamoto et al. teach translatable heating systems for biological samples; and Woudenberg et al. teaches an optical detection system for nucleic acid amplification. Applicant concludes that the combined references do not teach all of the claimed limitations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

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Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner maintains that the combined teachings of the references as set forth in the prior art rejection above results in a device and method of use that encompasses all of the claim limitations since the resulting structure would include an independently translatable sample block, an independently translatable well tray holder and an optical detection system in which the sample tray is positioned during the thermal cycling and optical detection processing steps.

Applicant next argues that there is no motivation or suggestion to combine the references. Applicant stresses that the references of Lurz et al., Pfoest et al. and Yamamoto et al. do not teach an optical detection system. Applicant further stresses that the references of Pfoest et al. and Yamamoto et al. are merely concerned with incubation and do not require an optical detection system. With respect to the reference of Woudenberg et al., Applicant argues that Woudenberg et al. does not teach an independently translatable sample block assembly and provides no motivation for the assembly to become translatable. Applicant takes the position that one of ordinary skill in the art would not modify the reference of Woudenberg et al. with a translatable sample block because the optical system of Woudenberg et al. provides a lid for positioning the sample tray on the stationary sample block assembly. In view of the deficiencies discussed above, Applicant concludes that the prior art does not provide motivation or suggestion to combine the references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of Lurz et al. discloses a thermal cycling device that includes a translatable sample block assembly. The reference does not disclose an optical detection system or an independently translatable sample well tray holder. Had the reference disclosed these additional claims limitations, the claims would have been rejected under 35 USC 102 rather than 103. With respect to the modification of Lunz et al. in view of the disclosure of Woudenberg et al., the reference of Woudenberg et al. was merely relied upon as a teaching that it is known in the art to optically monitor a sample during nucleic acid amplification not as a teaching of using an optical detection system with a translatable sample block. In view of this disclosure and based on the fact that the reference of Woudenberg et al. positions the optical detection system over the sample tray, one of ordinary skill in the art would have clearly recognized that the same optical detection system positioned in lid (12,13) of Lurz et al. would provide the same benefit provided in the reference of Woudenberg et al., optical monitoring of the amplification reaction. With respect to the use of an independently translatable sample well tray holder, the references of Pfost et al. and Yamamoto et al. both disclose to one of ordinary skill in the art that it is known in the art to employ an independently translatable sample well tray holder with an independently translatable sample block assembly. Both references disclose that the independently translatable sample well tray holders allows the samples to be process automatically prior to introduction into the area with the sample block assembly. As a result, one of ordinary skill in the art would recognize and/or be motivated to provide the system of the modified primary reference of Lurz et al. with an independently translatable sample well tray

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holder for the same reasons as disclosed in the references of Pfoest et al. and Yamamoto et al. providing a means recognized in the art for automating the sample preparation prior to introduction in the position with respect to the sample block assembly.

Finally, Applicant argues that there is no reasonable expectation of success with respect to the combination of the references because optics require fine tuned alignment to operate and the mechanical means disclosed by the references of Pfoest et al. and Yamamoto et al. do not require fine tuned alignment.

In response, Applicant's comments are not found to be persuasive because the reference of Woudenberg et al. is silent as to the requirement of "fine tuning". As shown in Figure 1 of Woudenberg et al., it appears that the sample vessel merely needs to be positioned under the optical detector without any precision since the detection can be made anywhere within the sample solution. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., fine-tuning) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note the instant claims merely recite that the sample well tray holder is independently translatable to position the samples into alignment with the optical detection system. The mechanical system of the references of Pfoest et al. and Yamamoto et al. are clearly capable of such alignment and/or precision, if not, the sample preparation of adding reagents and samples to the wells of the tray would not be capable of being performed. The alignment required for sample preparation would be equivalent to that required for aligning the optical detectors of Woudenberg et al. with the sample wells.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB